

**REMARKS**

Reconsideration of this application is respectfully requested.

Solely to expedite prosecution, applicants have canceled claims 57-60 and 65-86. Claims 87 and 88 are new and are derived from claims 61 and 62, but are not written in "product-by-process" format to stress the patentable features of the claimed invention. No new matter is introduced through this amendment.

Upon amendment, claims 61-64, 87, and 88 are pending in this application.

Applicants address the rejections of these claims below.

**Double Patenting Rejections**

Claims 61-64 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 92-127 and 130 of Appln. No. 09/225,233. Applicants have canceled claims 92-127 and 130 in Appln. No. 09/225,233. Accordingly, this rejection is moot.

Claims 61-64 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,525,243 B1; claims 1-10 and 13-21 of U.S. Patent No. 6,147,276 B1; and claims 11-18 of U.S. Patent No. 6,252,133 B1. Solely to expedite allowance of the pending claims, and not in acquiescence to this rejection, applicants will submit Terminal Disclaimers in compliance with 37 C.F.R. § 1.321(c) when the claims are otherwise indicated to be allowable.

**Rejections under 35 U.S.C. § 101**

Claims 61-64 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The Office contends that the pending claims do not

sufficiently distinguish over naturally occurring mammals and “lack evidence of the hand-of-man.” (Paper No. 20 at 7.)

Applicants traverse the rejection. Applicants’ claims are directed to a “clone” of a pre-existing, parental mammal. Such a “clone” requires asexual reproduction. See *American Heritage College Dictionary* (third edition) at 263 (defining clone as “an organism descended asexually from a single ancestor, such as a plant produced by layering”). Nature does not make “clones” of parental mammals because mammals do not reproduce asexually in nature. Since applicant’s claims require asexual reproduction of a mammal, the hand of man is clearly required for applicants’ “clone.” Accordingly, applicants respectfully request withdrawal of the rejection.

**Rejections under 35 U.S.C. § 102(b) and/or 103(a)**

Claims 61-64 were rejected under 35 U.S.C. § 102(b) and/or 103(a) over several publications that teach the production of embryos and mammals. (Massey, 1991; Campbell and Marshall, 1975; and Sims et al., 1991). It is the Office’s position that the mammals of the prior art anticipate or make obvious applicants’ claimed clones because there is no patentable distinction between the prior art mammal and a clone of that mammal. The Office contends that differences in age between the clone and the parent do not provide a new property/phenotype that makes the clone distinct from the prior existing mammal.

Applicants traverse the rejection. The relative difference in age between the clone and the parent of the clone **does** provide a new property/phenotype that makes the clone distinct from the prior existing mammal. Applicants’ claimed clone is a time-delayed copy of its parent. This time-delay is an important aspect of applicants’

discovery and provides a phenotypic distinction between applicants' clones and the mammals of the prior art.

The Office cannot simply ignore this distinction based on the premise that applicants' claims are "product-by-process claims." First, applicants' process generates a feature in the resultant mammal that is unique, namely, the resultant mammal is a time-delayed copy. Since the process generates this unique feature in the resultant mammal, patentable weight must be given to the process recited in claims 61-64. (See M.P.E.P. § 2113.) Second, claims 61-64 and new claims 87 and 88 recite a "clone." New claims 87 and 88 are not "product-by-process claims." The Office's equating a "clone" with "a method of making by somatic cell nuclear transfer" (Paper No. 20 at 16) is in error. As discussed above, a clone is "an organism descended asexually from a single ancestor." Thus, the term "clone" in claims 61-64, 87, and 88 does not, by itself, attach any process limitations to these claims, but serves as a structural limitation that distinguishes applicants' claimed mammals from those of the prior art.

The Office alleges that "age" or "age difference" is not a phenotype. However, according to a definition cited by the Office, phenotype is "the appearance or physical structure of an individual." (Paper No. 20 at 14.) According to *American Heritage College Dictionary* (third edition), "phenotype" is "the observable physical or biochemical traits of an organism, as determined by both genetics and environment." "Age" would certainly fall within both of these definitions of phenotype since age is part of "the appearance" and "the observable physical traits" of a mammal. For this reason, a three-year-old mammal would appear older than a new-born mammal. Thus, age is a phenotypic distinction between applicants' clones and the mammals of the prior art.

Moreover, regardless of whether the Office considers an age difference to be a “phenotypic” difference, the reduction in relative age of a clone as compared to its parent is a patentable distinction that cannot be ignored by the Office.

The Office’s example of a mother cow and its calf differing in age ignores another important aspect of applicants’ invention. Applicants’ claimed mammal is a “clone” of the parental mammal. Thus, due to asexual reproduction, applicants’ claimed “clone” has a genetic relationship to its parent unlike a mother cow and its calf. The calf, due to sexual reproduction, would only inherit half of its chromosomes from its parent. In this respect, it is not a copy of its mother. On the other hand, applicants’ clone would inherit all of its chromosomes from its parent. In this respect, it is a copy of its parent. This property of applicants’ claimed mammal cannot be ignored by the Office.

As discussed above, applicants’ process generates features in the resultant mammals that cannot be found in the prior art mammals. The features of applicants’ “clones” exhibit themselves at, at least, two different levels. First, applicants’ “clones” are copies of a pre-existing mammal. This means that, excluding the parental mammal, they are genetically unlike any other mammal that previously existed. Second, they are a time-delayed copy of the parental mammal. This means that they will always be younger than the parental mammal. This combination of features assures that applicants’ cloned mammals are distinct from any mammal that previously existed including the parental mammal. Consequently, applicants’ claimed invention cannot be anticipated by or obvious over the prior art.

The Office relies on *Ex parte Gray*, 10 U.S.P.Q.2d 1922 (Bd. Pat. App. & Inter. 1989) for the proposition that “the dispositive issue is whether or not the factor of the

claims exhibited any unexpected properties compared with the factor of the prior art” and concludes that “the cloned mammals and cloned mammalian embryos have not been shown to have any unexpected properties over the mammals and mammalian embryos of the prior art.” (Paper No. 20 at 18-19.) The Office’s conclusion is in error.

Applicants’ clone is a *time-delayed copy* of a pre-existing mammal. The combination of these two features (a copy and time-delay) results in applicants’ clones having unexpected properties. Applicants’ clone has the same chromosomes as a single parent mammal. Since mammals reproduce sexually, this can hardly be said to be an expected property of a progeny mammal. In this way, applicants’ clone is different than any other previously existing mammal except for its parent.

Applicants’ clone differs from its parent in that it must be younger than its parent and exists during a different time period than its parent. This is due to the time-delay inherent in cloning by somatic cell nuclear transfer. Thus, in relation to its parent, applicants’ clone exhibits unexpected properties. Namely, it has the same set of chromosomes, but is younger.

Consequently, applicants’ clone fulfills the criteria set forth in *Ex parte Gray* in that it exhibits unexpected properties compared with the mammals of the prior art. Accordingly, applicants respectfully request withdrawal of the rejection.

### **Conclusion**

Applicants respectfully submit that this application is now in condition for allowance. If the Examiner believes that issues remain to be addressed before a Notice of Allowance, applicants respectfully request that the Examiner contact the undersigned to discuss any outstanding issues.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

Dated: May 7, 2004

By: \_\_\_\_\_

  
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